

Coronary Artery Disease and FFR



ST. JUDE MEDICAL

MORE CONTROL. LESS RISK.

Module Content

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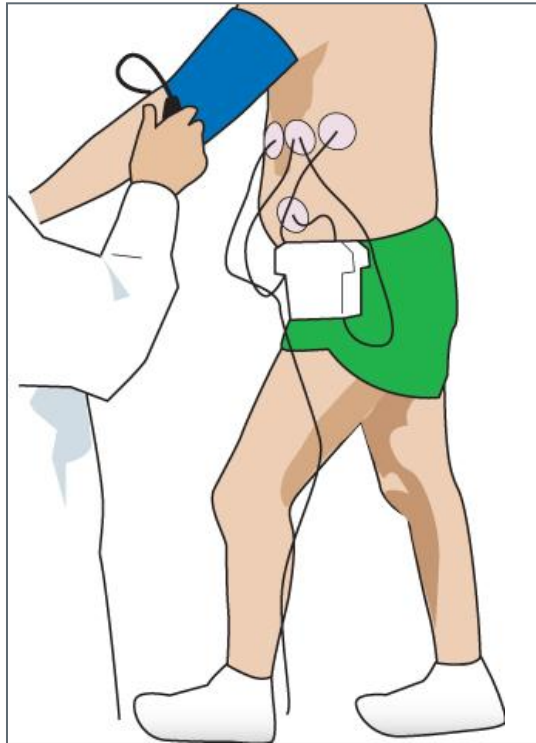
Symptoms

- A patient contacts his physician because he experiences chest pain during physical exercise.



At the Doctor

- If the physician suspects heart disease after have performed an exercise test (e.g. ECG while walking on a treadmill) he refers the patient for a coronary angiogram.



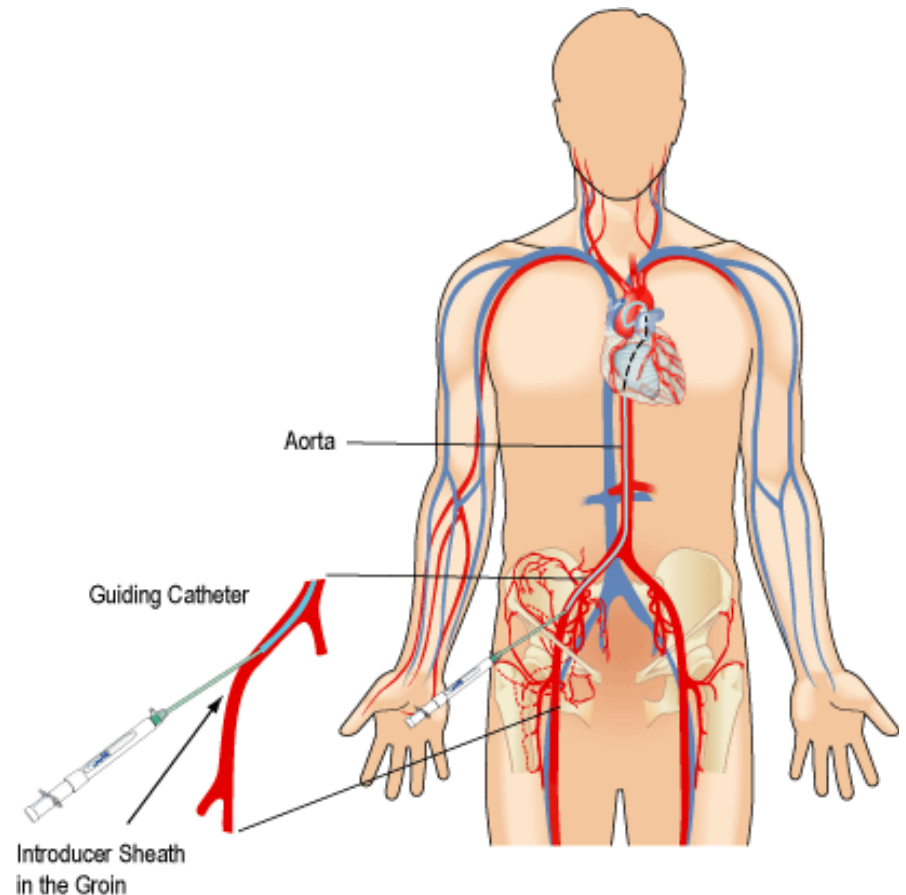
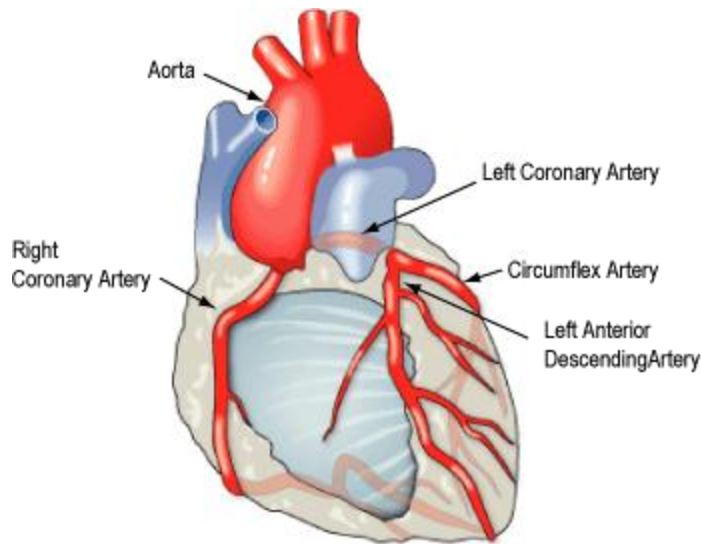
In the Cath Lab

- The patient goes to the coronary cath lab for an angiogram to check for narrowings in the arteries.



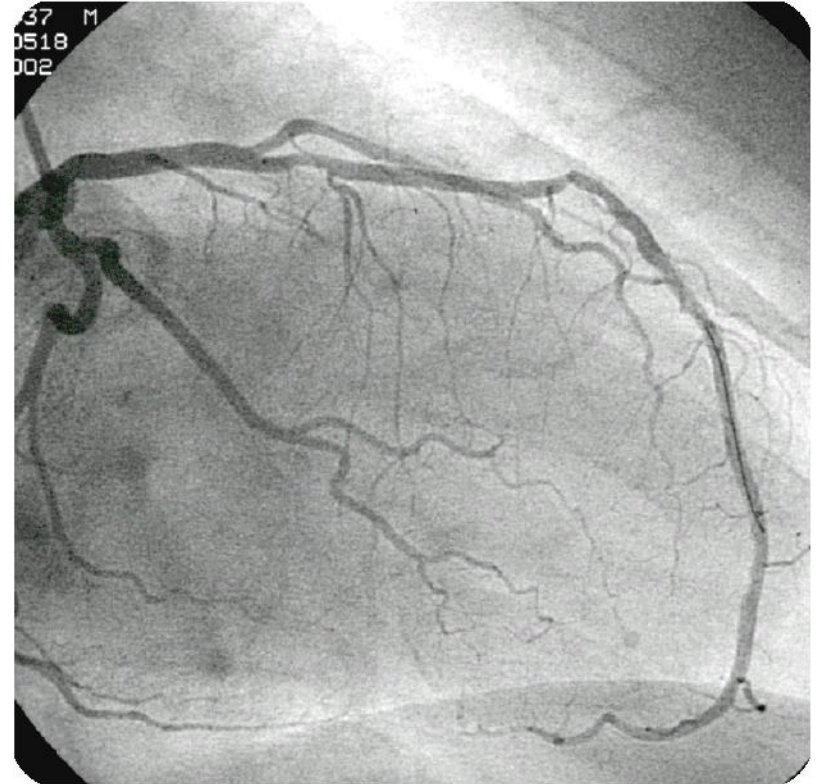
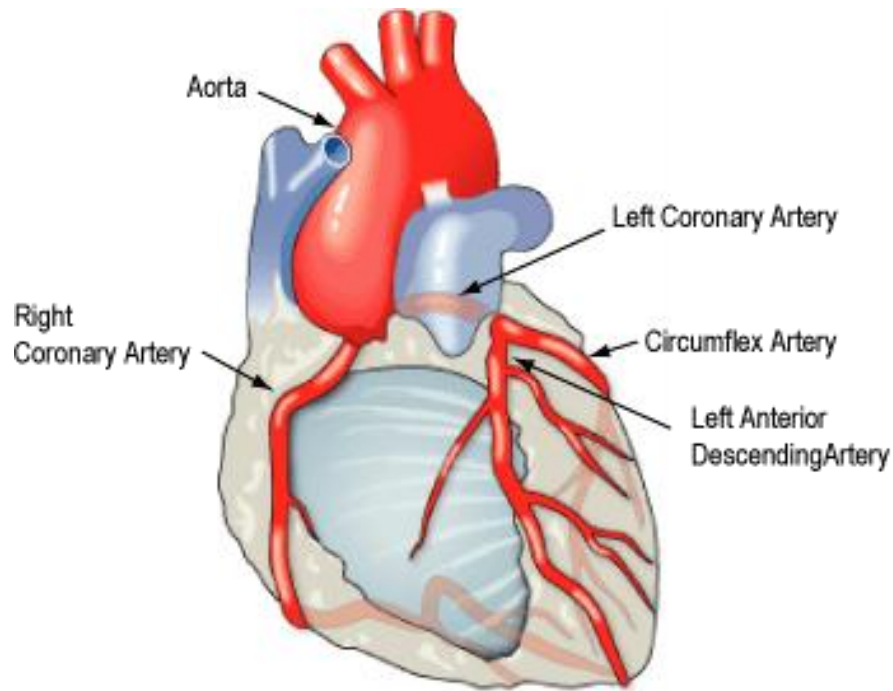
Cardiac Catheterization

- X-ray opaque liquid is injected into the coronary arteries to be able to view them "live" on a screen.



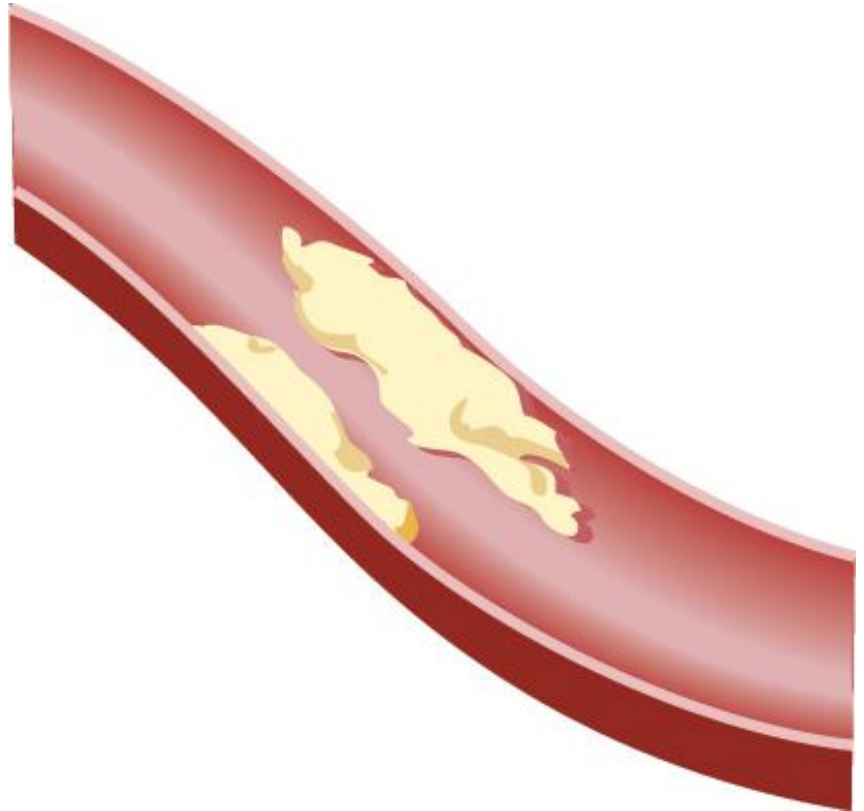
Cardiac Catheterization

- The angiogram shows an image of the coronary arteries.



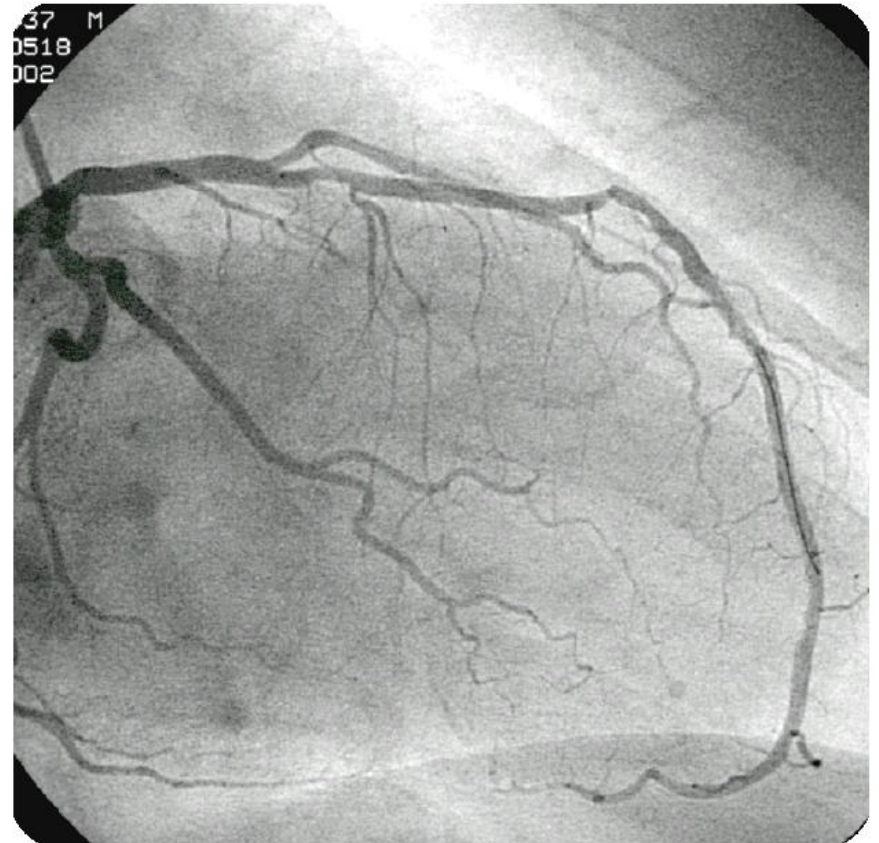
Cardiac Catheterization

- The images might show some disease in one or more of the major coronary arteries.



What Does an Angiogram Reveal?

- Are all the narrowings serious enough to require treatment? Which one is causing the patient's symptoms?



Treatment Alternatives

- If none of the vessels have really severe narrowings:
 - Medication only?
- If all 3 vessels are severely narrowed:
 - Bypass surgery?
- If only 1 or 2 of the vessels are severely narrowed:
 - One or more coronary stents?

Decision Making

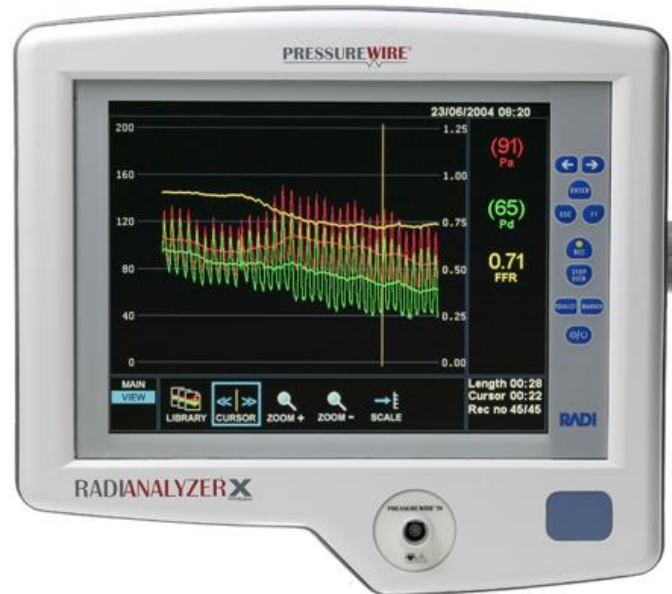
- The cardiologist may use FFR to help make a decision.



Equipment Required



PressureWire Sensor
to measure pressure
inside the coronary arteries



RadiAnalyzer Xpress
to calculate the results of
pressure measurements and
show them on a screen

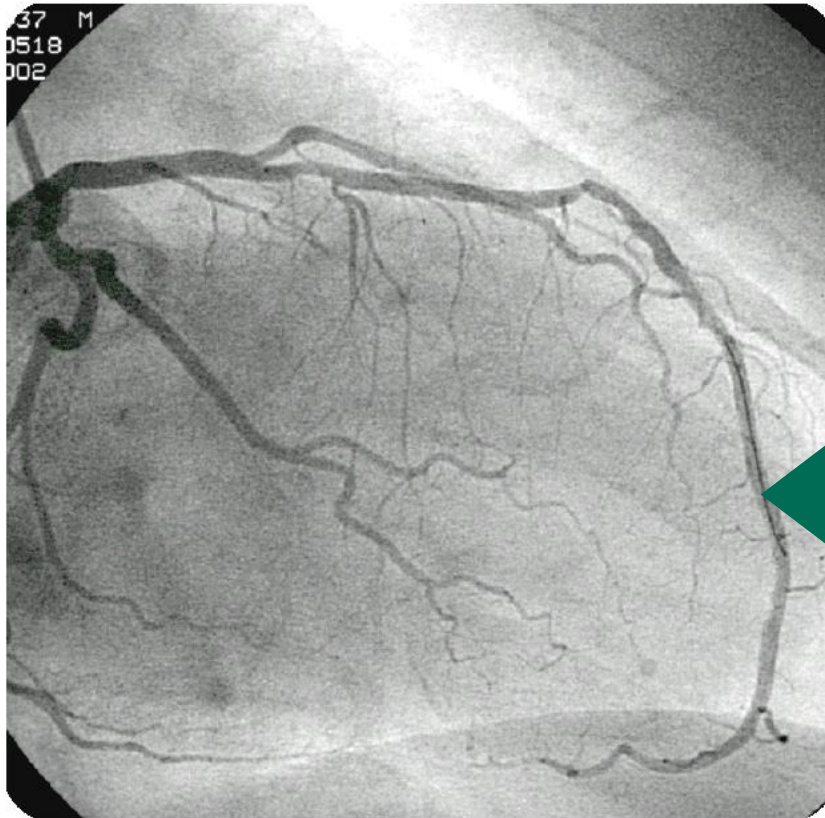


Hyperemic drug
to simulate exercise



FFR

- PressureWire sensor is placed inside the coronary artery, positioned beyond the narrowed area.

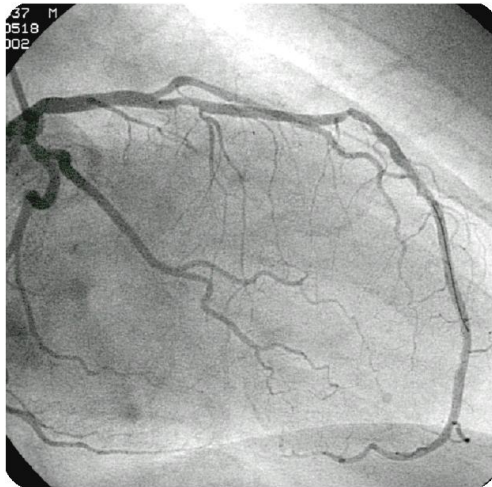


PressureWire Sensor
in the artery.

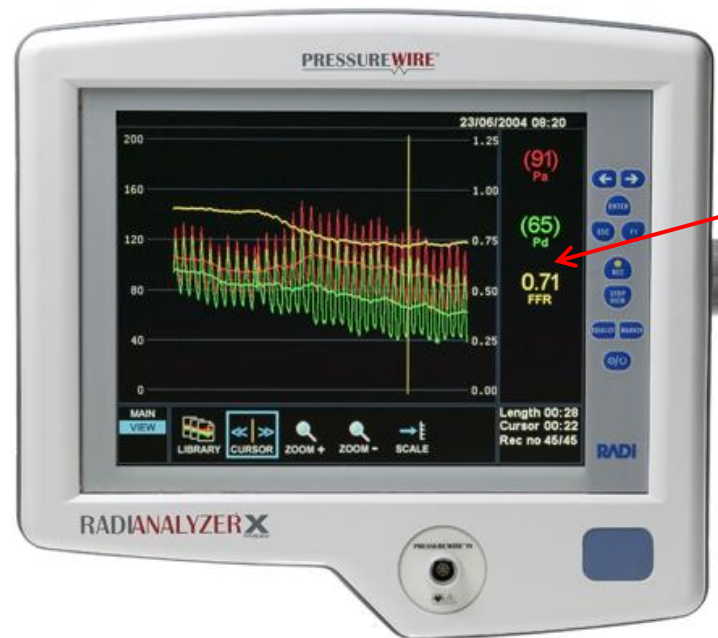


FFR

- Hyperemia is induced to simulate exercise. RadiAnalyzer Xpress then calculates how much the narrowing is impeding blood flow at maximum exercise.



Pressure is measured beyond the narrowings.

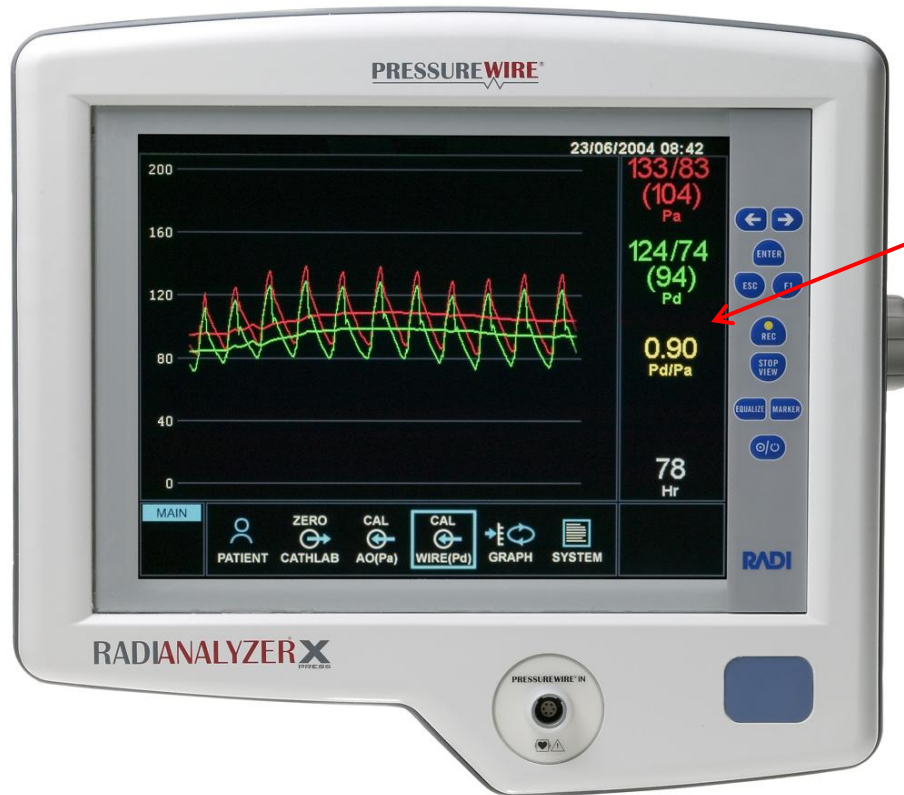


FFR result



CUT-OFF

- If FFR is above 0.75, the blood flow past the narrowing is at least 75% normal.



FFR >0.75:
This narrowing is very unlikely* the cause of the patient's symptoms.¹

* Sensitivity 88%

"Measurement of fractional flow reserve to assess the functional severity of coronary-artery stenoses."

Pijls, N. H. et al, N Engl J Med : 1996; 334: 26: 1703-1708



CUT-OFF

- If FFR is lower than 0.75, then the flow of blood able to get past the narrowing is less than 75%



FFR ≤ 0.75 :
This narrowing needs
to be treated.

* Specificity 100%


“Measurement of fractional flow reserve to assess the functional severity of coronary-artery stenoses.”

Pijls, N. H. et al, N Engl J Med : 1996; 334: 26: 1703-1708



Validation

- FFR has been thoroughly validated in scientific studies:

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Measurement of fractional flow reserve to assess the functional severity of coronary-artery stenoses

Pijls, N. H, J. *et al*, New England Journal of Medicine 1996 ; 334; 26: 1703-1708

"Fractional Flow Reserve A Useful Index to Evaluate the Influence of an Epicardial Coronary Stenosis on Myocardial Blood Flow"
Pijls et al, Circulation 1995;92:3183-3193.



Validation

FFR has been further validated in scientific studies in the following clinical conditions:

- Multivessel Disease
- Left Main Disease
- Serial Lesions
- Acute Coronary Syndromes
- Bifurcations/jailed side-branches
- Post stent assessment



Complement To Angiography

- FFR has been proven superior to angiography alone:

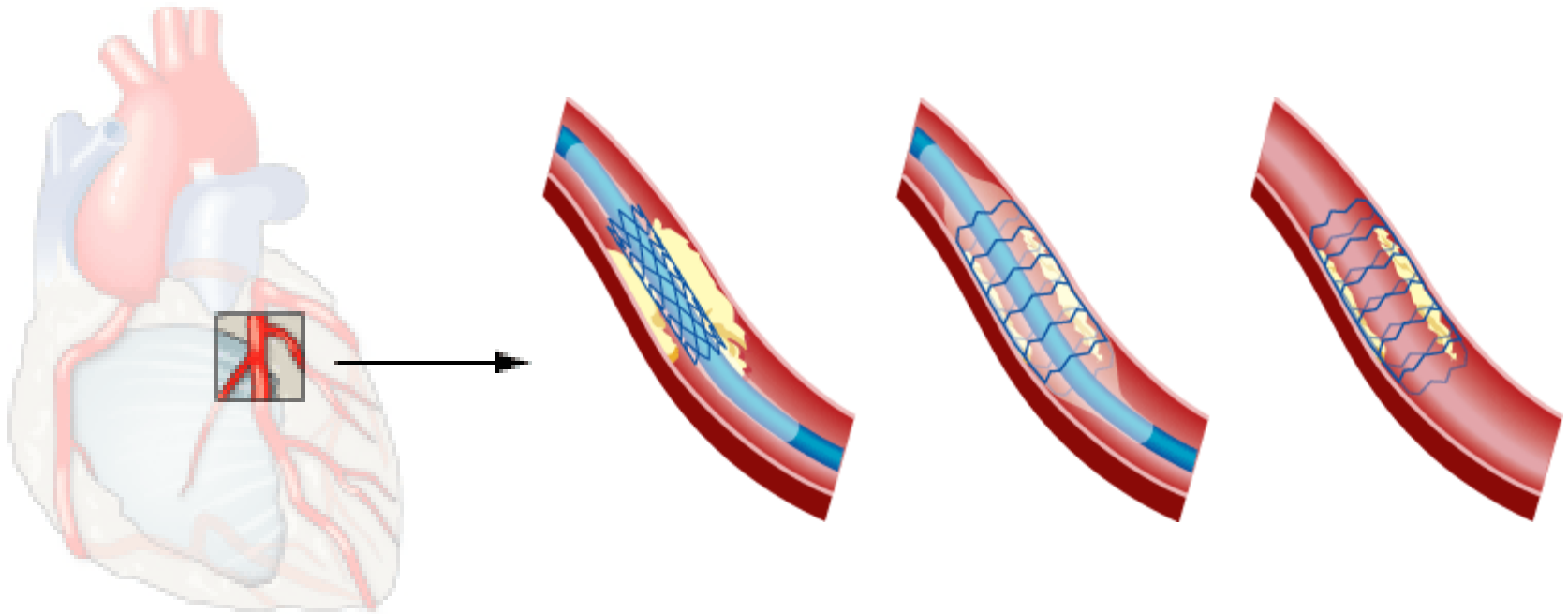
Study showed that visual assessment of an angiogram by experienced interventional cardiologists cannot accurately predict the significance of most moderate narrowings.

Experienced physicians were wrong in their visual estimations about 50% of the time. The specificity of visual assessment was only 47% compare with FFR: 100%.

Brueren, B. R et al, International Journal of Cardiology, 2002: 18; 2: 73-76

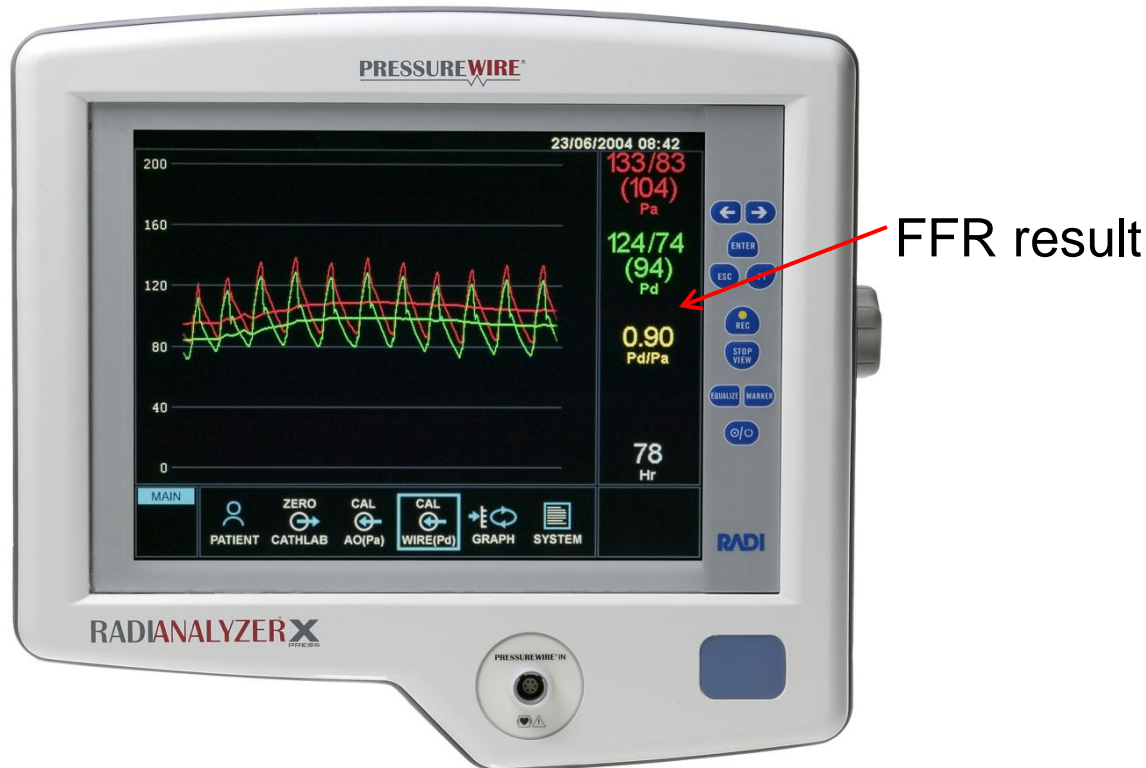
Intervention

- A stent may be placed in a coronary artery to open a narrowing.



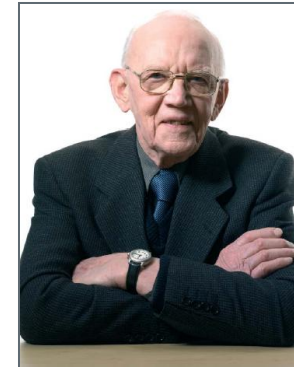
Checking Treatment Results

- Once a stent has been placed in the artery, the FFR should be as close as possible to 1.0.



Objective Proof

- The FFR results provide objective proof for the interventionalist, the patient, the referring doctor and the surgeon.



Optimal Treatment

- FFR helps the patient get the best treatment for their heart condition.



Rx Only

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Product referenced is approved for CE Mark

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